

**Roster of the FDA/CDRH Gastroenterology and Urology Devices Panel
December 2, 2010**

CHAIRPERSON

Karen L. Woods, M.D.
Clinical Associate Professor of Medicine
Baylor College of Medicine, Houston, TX

VOTING MEMBERS

Jason T. Connor, Ph.D.
Biostatistician
Berry Consulting, LLC, Orlando, FL

Christian P. Pavlovich, M.D.
Associate Professor, Brady Urological Institute
Johns Hopkins Medical Institutions, Baltimore, MD

TEMPORARY VOTING MEMBERS

Joseph J. Cullen, M.D.¹
Professor, Department of Surgery, Division of Gastrointestinal, Minimally Invasive & Bariatric
Surgery
University of Iowa, Iowa City, IA

Drew B. Schembre, M.D.
Chief, Division of Gastroenterology
Virginia Mason Medical Center, Seattle, WA

Steven D. Schwaitzberg, M.D.
Chief of Surgery
Cambridge Health Alliance, Boston, MA

Arnold Wald, M.D.
Professor of Medicine, Division of Gastroenterology and Hepatology
University of Wisconsin School of Medicine and Public Health, Madison, WI

INDUSTRY REPRESENTATIVE

Terry N. Layton, Ph.D.
Technical Officer, Biomedical Engineer
Laytech, Inc., Long Grove, IL

CONSUMER REPRESENTATIVE

E. Francine Stokes McElveen, J.D.
Senior Advisor to the President for Legal Affairs
Coppin State University, Baltimore, MD

PATIENT REPRESENTATIVE

Jo-Ellen De Luca¹

DESIGNATED FEDERAL OFFICER

Margaret McCabe-Janicki, B.S.
Center for Devices & Radiological Health
Food and Drug Administration, Silver Spring, MD

¹ Dr. Cullen and Ms. De Luca are consultants to the FDA/CDER Gastrointestinal Drugs Advisory Committee.

PANEL BIOGRAPHIES**Karen L. Woods, M.D.**

Dr. Woods is a gastroenterologist at The Methodist Hospital in Houston, TX. Dr. Woods has served as the Elected Secretary of the Medical Staff at The Methodist Hospital since 2009, and she has served on numerous medical staff committees. She also holds an appointment as Clinical Associate Professor of Medicine at Baylor College of Medicine, Department of Medicine, Gastroenterology Section. Dr. Woods earned her B.A. (Biology) and M.D. degrees at the University of Missouri - Kansas City, Kansas City, Missouri.

Jason T. Connor, Ph.D.

Dr. Connor is uniquely trained as a biomedical engineer and a Bayesian biostatistician. He works at a statistical consultant designing Bayesian adaptive clinical trials for Berry Consultants. He received his Ph.D. in Statistics & Public Policy from Carnegie Mellon University. He has coauthored over 50 papers in clinical journals. He recently finished a six-year term as an Associate Editor of The American Journal of Gastroenterology. Jason holds an Assistant Professor of Medical Education appointment at the University of Central Florida and was visiting professor at the Johns Hopkins University Bloomberg School of Public Health summer of 2010. He is a fellow of the American College of Gastroenterology.

Christian P. Pavlovich, M.D.

Dr. Pavlovich is an Associate Professor of Urology at Johns Hopkins, directs Urologic Oncology at Johns Hopkins Bayview Medical Center, and is Fellowship Director for the Johns Hopkins Urologic Oncology Fellowship. Dr. Pavlovich trained in Urology at Cornell/New York Hospital, then did a 2-year fellowship at the National Cancer Institute in Bethesda prior to joining the Johns Hopkins faculty in 2001 where he is a busy minimally-invasive cancer surgeon who treats primarily prostate, kidney, and bladder malignancies. In addition, he has maintained NIH and Department of Defense funding for research work identifying urinary markers for prostatic disease. He currently has over 70 publications relating to the diagnosis, treatment, and prognosis of patients with urologic disease.

Joseph J. Cullen, M.D.

Dr. Cullen is a Professor of Surgery at the University of Iowa and Chief of Surgical Services at the Iowa City VA Medical Center. He finished his surgery residency at the University of Iowa in 1991 and did a NIH research fellowship in digestive diseases at the Mayo Clinic from 1991-1993. He is currently funded from the VA Merit review program and the NIH. He has published more than 100 papers in peer review journals and over 20 book chapters.

Steven D. Schwartzberg, M.D.

Dr. Schwartzberg is Chief of Surgery at the Cambridge Health Alliance and Associate Professor of Surgery at Harvard Medical School. He is a former IRB chair and has written extensively in the field of device and procedure innovation. He is the incoming president of the Society of American Gastrointestinal and Endoscopic Surgeons. Dr. Schwartzberg is a graduate of the Johns Hopkins University and Baylor College of Medicine.

Arnold Wald, M.D.

Dr. Wald is currently Professor of Medicine in the Division of Gastroenterology and Hepatology at the University of Wisconsin School of Medicine and Public Health in Madison. Most of his professional career was spent at the University of Pittsburgh Medical Center from 1978 before moving to Wisconsin in January 2006. He has had a longstanding interest and an international reputation in disorders of GI motility and functional GI disorders with a particular emphasis in colorectal and pelvic floor disorders. He is the author or co-author of over 300 articles, book chapters and abstracts in his field of interest.

Terry N. Layton, Ph.D.

Dr. Layton is a Biomedical Engineer who started his career as a design engineer for urological medical devices in 1975. He now is a technical executive with Laytech, Inc actively involved in product design, regulatory approval, and clinical evaluation for new health care markets and business ventures. In addition to his involvement in the medical device industry, he also is a Visiting Professor at the University of Illinois, Chicago Department of Bioengineering teaching classes on medical device industry 'skill sets' and consults in technology assessment for both private and government organizations.

E. Francine Stokes McElveen, J.D.

Ms. Stokes McElveen serves as the Senior Advisor to the President for Legal Affairs at Coppin State University, a constituent institution of the University System of Maryland. She provides legal advice and counsel to executive officers, directors and other senior academic and administrative leaders regarding a broad range of laws, regulations, risk and policies that impact the institution. Prior to coming to Coppin State University, Ms. Stokes McElveen served as an assistant to the President of Morgan State University for government and state relations. She is also a former assistant State's Attorney for Baltimore City.

Jo-Ellen De Luca

Ms. De Luca is an IBD and Rectal Cancer Survivor and an active GI Patient Advocate, having served the NCCTG GI Committee for over 8 years, as well as service to AIBS/DoD along with numerous FDA panels in the past. In her home community, Ms. De Luca founded and manages "Get Checked!" which is our country's largest GI cancer support group.

Margaret McCabe-Janicki, B.S.

Ms. McCabe-Janicki holds a Bachelor of Science in Chemistry with a concentration in German. She has worked for FDA since 2003, first as a chemist at FDA's Center for Biologics Evaluation and Research in the Office of Vaccines Research and Review (OVR), and then as CBER's Institutional Animal Care and Use Committee Coordinator. Margaret now serves as CDRH's Designated Federal Officer for the Gastroenterology and Urology, General and Plastic Surgery, and Hematology and Pathology Devices Panels, and for the Devices Good Manufacturing Practice (GMP) Advisory Committee.